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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,886	SEGAL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/19/03, 2/17/04, 5/14/04 + 7/05/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-11* is/are rejected.

7)☒ Claim(s) *1-3 and 5-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/27/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of:

a vaccine composition comprising a cell and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a cell-surface binding moiety and a second amino acid sequence comprising a ligand for a cell surface polypeptide; wherein the elected cell is a mammalian cell, the ligand is a ligand for a cytokine receptor, wherein the cytokine is GM-CSF;

in the reply filed on 07/05/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Additionally, Applicant is reminded that the restriction requirement issued 02/17/2005 is a restriction among multiple patentably distinct inventions, not an election of species.

Status of Claims

3. Claims 1-11 are pending. Claim 4 is withdrawn from examination because the claim is directed to a ligand for CD40, and not a ligand for a cytokine receptor as elected. Claims 1-3 and 5-11 are under examination.

Specification

4. The abstract of the disclosure is objected to because the disclosure provides two different abstracts. It is not readily apparent if the abstract provided on page 201 or page

976 of the disclosure is the preferred abstract for the claimed invention. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: The term "effector" is misspelled as "effeector" in last sentence, last paragraph, page 1 of the disclosure. Appropriate correction is required.

Claim Objections

6. Claims 1-3 and 5-11 are objected to because of the following informalities: the recitation "a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte" is objected. In the instant, the recitation is awkwardly presented. It is believed that the intended meaning of the recitation is "a second amino acid sequence comprising the amino acid sequence of a ligand for a cell surface polypeptide of a leukocyte". However, as presented, the recitation does not immediately transmit such intention.

7. Also, claims 6-7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The claims depend on claim 5. Claim 5 clearly limits the cell to a tumor cell, a virus, a bacterial cell, a fungal cell, a cell of a parasite, a prion, a mammalian cell, an insect cell, or a polypeptide free of other cell-derived material. However, claims 6-7 require that the cell be pathogenic and attenuated, respectively. A pathogenic and attenuated cell is not part of one of many selections that is provided in claim 5. Hence,

the claims fail to further limit the parent claim. For the purpose of advancing prosecution, it is presumed that the claims are directed at an attenuated and pathogenic mammalian cell.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "further comprises some of said polypeptide which is not bound to said cell" renders the claims indefinite. It is not clear what "some" encompasses. The term "some" is imprecise. It is unclear how much of the polypeptide is considered as "some" and which portion of the polypeptide is covered by "some". Therefore, it renders the claims indefinite.

Additionally, the recitation "at least about" in line 1 of claim 3 also renders the claim indefinite. It is unclear as to what range of specific activity is covered by the term "about" in the recitation "at least about". For the purpose of a prior art search, the cited recitation is substituted with the recitation "at least".

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed at a vaccine composition that comprises the following formulation: a) a cell, and b) a fusion polypeptide. It is recognized the fusion protein acts as an adjuvant in the claimed vaccine composition, and the cell is the active ingredient that provides protective immunity against a disease, infection and/or certain non-desired condition.

Thus, the claimed invention is directed at a broad genus of vaccines that provide protection for conditions: viral infection, parasitic infection, bacterial infection, autoimmune diseases, allergy, graft rejections, cancer...etc. In the instant, because the protective property of the claimed vaccine composition is provided by the cell, which is recognized as the active ingredient that provides protective immunity against a disease, infection and/or certain non-desired condition; the instant written description analysis will focus on the lack of adequate written description for the cell. In the absence of adequate written description for the cell, adequate written description for the claimed vaccine composition would also be lacking.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient description of a representative number of species by i) actual reduction to practice, ii) reduction to drawings, or iii) disclosure of

relevant identifying characteristics. Examples of factors to be considered for the latter requirement include:

- disclosure of complete or partial structure,
- physical and/or chemical properties,
- functional characteristics,
- correlation between structure and function, and
- methods of making.

Each of the listed criteria is addressed in turn below.

i) sufficient description of a representative number of species by actual reduction to practice: In the instant, the claims are directed to a genus of cells that provide protective immunity for conditions: viral infection, parasitic infection, bacterial infection, autoimmune diseases, allergy, graft rejections, cancer...etc.

The specification provides a generic list of cells that could be use as the cells for the claimed vaccine composition. The list includes malignant cells, benign tumor cells, lymphocytes, e.g. B or T lymphocytes which may be pathogenic and/or autoreactive, cells expressing an antigen from an exogenously introduced nucleic acid molecule, eukaryotic cells such as mammalian cells, human cells, fibroblasts, insect and fungal cells, and prokaryotic cells such as bacterial cells. The specification also provides a long list of conditions that the claimed vaccine is intended to provide protection. However, among the items listed in the specification, only two specific cells are disclosed as having the ability to provide protective immunity against a disease, infection and/or certain non-desired condition. The cells that the specification teaches are: irradiated CMS-5

fibrosarcoma cells and B16F10 melanoma cells. The irradiated CMS-5 fibrosarcoma cells are able to provide protection to mice against fibrosarcoma growth. And the irradiated B16F10 melanoma cells are able to provide protection to mice against melanoma growth.

Of the number of species envisioned to be encompassed by the genus of cell that provide protective immunity against a disease, the two cells disclosed by the specification is too low of a number to sufficiently describe the representative number of species.

Thus, the actual reduction to practice that is provided by Applicant, particularly in working examples number 6 and 16-19, does not sufficiently describe the genus of cells that provide protective immunity against a disease, infection and/or certain non-desired condition.

ii) sufficient description of a representative number of species by reduction to drawings: The specification does not contain any drawings. Thus, there is insufficient description of a representative number of species by reduction to drawings.

iii) sufficient description of a representative number of species by disclosure of relevant identifying characteristics:

- disclosure of complete or partial structure: Neither a complete or partial structure is provided for the cell. No structural data for the cell is noted in the specification.
- physical and/or chemical properties: From the two cells that provide mice protection against tumor growth, it is gathered that the physical properties that is required for cells that provide mice protection

against tumor growth is irradiated tumor cells, i.e., irradiated CMS-5 fibrosarcoma cells and B16F10 melanoma cells. However, because the observed physical and/or chemical properties are derived from only a few numbers of species when compared to the genus as a whole, it cannot be concluded that the observed physical and/or chemical properties are representative of the entire genus of cell.

- functional characteristics: The cell is expected to provide protection against for conditions: viral infection, parasitic infection, bacterial infection, autoimmune diseases, allergy, graft rejections, cancer...etc.
- correlation between structure and function: The specification does not provide a correlation between the required or expected functional characteristic and the structure that is responsible for the required or expected functional characteristic.
- methods of making the claimed product: Beside the two noted cells provided by the specification, the specification does not disclose of method of making any other cells.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that

[he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the chemical structure of the cell that is used as the active ingredient in providing protection in the claimed vaccine composition, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making the cell. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the vaccine compositions comprising irradiated CMS-5 fibrosarcoma cells or irradiated B16F10 melanoma cells as the cells, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

12. Claim 3 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant rejection is targeted at the limitation recited in claim 3.

The claim requires the second amino acid sequence having at least five contiguous amino acids of a naturally occurring cytokine, specifically GM-CSF.

While it is stated above that it is the fusion protein that acts as an adjuvant in the claimed vaccine composition; however, it is recognized from teachings that are primarily provided in the specification and the art that the cytokine is the active component that provides the adjuvant activity.

Thus, the claim is drawn encompass second amino acid sequence having at least five contiguous amino acids of a naturally occurring GM-CSF, and function as an adjuvant. In the instant, the requirement is directed at a genus of polypeptides that is defined only by sequence identity and a function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient description of a representative number of species by i) actual reduction to practice, ii) reduction to drawings, or iii) disclosure of relevant identifying characteristics. Examples of factors to be considered for the latter requirement include:

- disclosure of complete or partial structure,
- physical and/or chemical properties,
- functional characteristics,
- correlation between structure and function, and
- methods of making.

Each of the listed criteria is addressed in turn below.

i) sufficient description of a representative number of species by actual reduction to practice:

In the instant, the specification only teaches of the full GM-CSF polypeptide. The specification does not teach of a single amino acid sequence that is less that full GM-CSF polypeptide. Ergo, the specification does not provide for sufficient number of species by actual reduction to practice.

ii) sufficient description of a representative number of species by reduction to drawings: The specification does not contain any drawings. Thus, there is insufficient description of a representative number of species by reduction to drawings.

iii) sufficient description of a representative number of species by disclosure of relevant identifying characteristics:

- disclosure of complete or partial structure: While the complete structure of the naturally occurring GM-CSF polypeptide is not provided in the specification, a complete structure of the polypeptide can be readily ascertain from the art. However, no partial structures of the GM-CSF polypeptide are provided in the specification, not to mention those that can be use as an adjuvant.
- physical and/or chemical properties: The only two physical and/or chemical properties that are provided in the specification is that the second amino acid is required to have at least 5 contiguous amino acids of GM-CSF.
- functional characteristics: From the disclosure and the art, it is gathered that the second amino acid sequence is the active component that provides the adjuvant activity.

- correlation between structure and function: The specification does not provide a correlation between the required or expected functional characteristic and the structure that is responsible for the required or expected functional characteristic.
- methods of making the product: Beside the complete GM-CSF polypeptide, the specification does not disclose of method of making any second amino acid sequences that comprises at least 5 contiguous amino acid sequences of GM-CSF, not to mention those that can be use as an adjuvant.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the chemical structure of the second amino acid sequence that is used as an adjuvant in the claimed invention, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making the second amino acid sequence. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The compound itself is

required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the complete sequence of GM-CSF, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

13. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph because the specification is not enabling for the full scope that is instantly claimed. While the specification is enabling for:

> a vaccine composition comprising irradiated CMS-5 fibrosarcoma cells or irradiated B16F10 melanoma cells, and a fusion polypeptide, wherein the fusion polypeptide comprises the influenza hemagglutinin protein and the GM-CSF protein;

the specification does not reasonably provide enablement for the full breadth of the claimed invention:

> a vaccine composition for conditions: viral infection, parasitic infection, bacterial infection, autoimmune diseases, allergy, graft rejections, cancer...etc.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

MPEP § 2164.06(b) provides the following: In In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the 1983 application disclosed a vaccine against the RNA tumor virus known as Prague Avian Sarcoma Virus, a member of the Rous Associated Virus family. Using functional language, Wright claimed a vaccine "comprising an immunologically effective amount" of a viral expression product. Id., at 1559, 27 USPQ2d at 1511. Rejected claims covered all RNA viruses as well as avian RNA viruses. The examiner provided a teaching that in 1988, a vaccine for another retrovirus (i.e., AIDS) remained an intractable problem. This evidence, along with evidence that the RNA viruses were a diverse and complicated genus, convinced the Federal Circuit that the invention was not enabled for either all retroviruses or even for avian retroviruses.

In the instant, the claimed invention is amendable to that of In re Wright. Instead of claming a vaccine composition comprising a viral expression product, the claimed invention is directed at a vaccine composition that comprises a cell and an adjuvant (the fusion polypeptide recited in the claims).

The breadth of the claims encompasses a vaccine composition for conditions: viral infection, parasitic infection, bacterial infection, autoimmune diseases, allergy, graft rejections, cancer...etc. However, because it appears that the primary focus of Applicant's endeavor is directed at a cancer vaccine composition, e.g. working examples 16 and 18-19, the focus of the instant enablement analysis is cancer vaccine--even though the breadth of the claims extends well beyond cancer vaccines.

While the breadth of the claims extends well beyond cancer vaccines, the specification only teaches of two vaccine compositions. The first is attenuated (irradiated) CMS-5 fibrosarcoma cells decorated with the GP-GM-CSF-HA fusion polypeptide. The second is attenuated (irradiated) B16F10 melanoma cells decorated with the GP-GM-CSF-HA fusion polypeptide. In both instances, the vaccine compositions protect mice against tumor growth, specifically fibrosarcoma and melanoma growth, respectively. Hence, the specification is enabling for these two vaccine compositions.

However, beside the two vaccine compositions that the specification provides, the specification does not provide any additional vaccine compositions. No other working examples are provided to demonstrate that more than two vaccine compositions are made and used in the intended context that is instantly claimed. In the instant, the

specification provides a generic list of cells that could be use as the cells for the claimed vaccine composition. The list includes malignant cells, benign tumor cells, lymphocytes, e.g. B or T lymphocytes which may be pathogenic and/or autoreactive, cells expressing an antigen from an exogenously introduced nucleic acid molecule, eukaryotic cells such as mammalian cells, human cells, fibroblasts, insect and fungal cells, and prokaryotic cells such as bacterial cells. The specification also provides a long list of conditions that the claimed vaccine is intended to provide protection. However, among the items listed in the specification, only two specific cells are disclosed as having the ability to provide protective immunity against a disease, infection and/or certain non-desired condition. [The cells that the specification teaches are: irradiated CMS-5 fibrosarcoma cells and B16F10 melanoma cells. The irradiated CMS-5 fibrosarcoma cells are able to provide protection to mice against fibrosarcoma growth. And the irradiated B16F10 melanoma cells are able to provide protection to mice against melanoma growth.] No additional guidance, i.e., relevant identifying characteristics, is provided in the specification regarding other cells that can be use in conjunction with the claimed invention, i.e., those that provide protection against a specific ailment or group of conditions. Thus, the specification is not found to be enabling for any additional scope that is beyond the two vaccine compositions that it teaches.

Nor does the specification does not teach the skilled artisan how to overcome the complexities that hinder or defer the development of a cancer vaccine. The complexities that challenge the discovery of tumor vaccines include antigen change, immune escape, and the inability of target tumor antigen to induce a high level of immunogenicity, as

evidence by Yu et al.[1] Furthermore, at the time of filing for the instantly claimed invention, the state of the art notes that a cancer vaccine that can reliably increase a patient survival or induce tumor destruction does not exist. [Abstract of Yu et al.]

Furthermore, the specification does not teach the skilled artisan how to properly activate and prolong the activation of antitumor T cells, which is recognized in the art as the crucial missing piece of the immunotherapy--a method of treatment for cancer, puzzle an significant barrier in developing an effective therapeutic vaccine. [Last paragraph of Yu et al.]

In addition to the above provided summation on the state of cancer vaccine, Berzofsky et al.[2] also discusses several major hurdles that exist in the development of cancer vaccines. Though some of the hurdles that Berzofsky et al. discusses are the same as that of Yu et al., Berzofsky et al. provides a listing of other hurdles. These include: i) identification of antigens that focus the exquisite specificity of the immune system on cancer cells without harming normal cells; ii) development of methods to induce an immune response sufficient to eradicate the tumor in the face of self-tolerance to many tumor antigens; and iii) overcoming mechanisms by which tumors evade the host immune response. In the instant, the specification does not provide any guidance as to how the skilled artisan can overcome or circumvent the hurdles that are discussed by Berzofsky et al.

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[1] Yu et al. Cancer vaccines: progress reveals new complexities. The Journal of Clinical Investigation, 08/02, Vol. 110, No. 3, 289-294.
[2] Berzofsky et al. Progress on new vaccine strategies for the immunotherapy and prevention of cancer. The Journal of Clinical Investigation. June 2004, Vol. 113, No. 11, 1515-1525.

Moreover, the state of the art notes that to take advantage of the immune system's specification against cancer, the skilled artisan must find antigens that clearly mark the cancer cells as different from the host cells, as noted by Berzofsky et al. In the instant, no such teaching or guidance is provided in the specification. Additionally, the specification also does not teach the skilled artisan how to overcome instances where tumor antigens of interest are not expressed on the surface of the tumor cells, which is a challenge that has been encountered in the discovery of a cancer vaccine. [2nd paragraph, left column of page 1515, of Berzofsky et al.]

Thus, in view of the very limited teaching that is provided in the specification and the existence of many major challenges identified in the art pertaining to the development of a cancer vaccines, the skilled artisan would not know how to make and use the full scope of the claimed invention without undue experimentation.

Hence, the claims are rejected under 35 U.S.C. 112, first paragraph because the specification is not enabling for the full scope that is instantly claimed.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-3, 5-6 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbage et al.[3]

The claims are directed to a composition comprising a cell that is bound to a fusion polypeptide, wherein the polypeptide comprises i) a first amino acid sequence that comprises a cell-surface binding moiety, and ii) a second amino acid sequence, whereby the second amino acid sequence is a ligand for a cell surface polypeptide of a leukocyte.

The claims later limit i) the ligand to a ligand for a cytokine receptor, which is later limited to comprise at least 5 contiguous amino acids of a naturally occurring GM-CSF; ii) the cell to a pathogenic mammalian cell and mammalian cells that are unable to divide; and iii) the leukocyte be an antigen presenting cell, or a professional antigen presenting cell, which is further limited to a dendritic cell.

Burbage et al. teaches a composition comprising a cell and a fusion polypeptide.

Burbage et al. teaches a fusion polypeptide, wherein the polypeptide comprises i) a first amino acid sequence, and ii) a second amino acid sequence that is a ligand for a cell surface polypeptide of a leukocyte. The first amino acid sequence used by Burbage et al. is ricin. Ricin is a lectin. The ricin polypeptide use by Burbage et al. is noted to be capable of binding to a carbohydrate; ergo, it comprises a carbohydrate-binding domain, which are present on cells. Thus, the first amino acid sequence provided by Burbage et al. comprises a cell-surface binding moiety. [Title; and 1st full paragraph, left column of page 682]

The ligand that Burbage et al. teaches is GM-CSF. GM-CSF is a ligand for a cytokine receptor--GM-CSFR, which is a cell surface polypeptide of an antigen presenting cell, a professional antigen presenting cell, particularly dendritic cell.

Additionally, since Burbage et al. uses the GM-CSF polypeptide, the polypeptide would necessarily have at least five contiguous amino acids of a naturally occurring GM-CSF. Thus, Burbage et al. teaches a second amino acid sequence that is a ligand for a cell surface polypeptide of a leukocyte, and have at least 5 contiguous amino acids of a naturally occurring GM-CSF.

The cell that Burbage et al. teaches is a mammalian cell. The mammalian cells that Burbage et al. teaches include acute myeloid leukemia cells, K562 human chronic myeloid leukemia cells, and KB human epidemoid carcinoma cells. [first full paragraph on right column of page 684.] The cells, along with the fusion protein, are not suspended in a nutritive medium; in the absence of nutritive medium, cellular growth cannot occur. Thus, the cells used by Burbage et al. would not be able to substantially divide.

Thus, Burbage et al. teaches a composition comprising a cell and a fusion polypeptide. The cell of Burbage et al. is the same as that instantly claimed. The same is also observed for the fusion polypeptide. Thus, Burbage et al. teaches the claimed composition.

Although it is noted that Burbage et al. is silent on the binding of the first amino acid to the cell, however, because the first amino acid sequence of Burbage et al. is capable of binding to a carbohydrate domain and the cell of Burbage et al. does have a

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[3] Burbage et al. Ricin fusion toxin targeted to the human granulocyte macrophage colony stimulating factor receptor is selectively toxic to acute myeloid leukemia cells. Leukemia Research, 1997, Vol. 21 NO. 7,

cell-surface binding moiety-- a carbohydrate binding domain; the first amino acid sequence would necessarily bind to the cell.

Additionally, it is noted that the claims recite a "vaccine composition". The cited recitation has been considered, however, it is found that the recitation does not further limit the composition as claimed. The recitation "vaccine composition" suggests or makes optional the use of the composition as a pharmaceutical. However, it does not require steps to be formed or does not limit the claims to a particular structure. Thus, it does not limit the scope of the claims.

Thus, Burbage et al. anticipates the claimed invention.

16. Claims 1-2, 5-6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramshaw et al.[4]

The significance of claims 1-2, 5-6 and 9-11 is discussed above.

Ramshaw et al. teaches a composition comprising a cell and a fusion polypeptide. [Lines 55-62 of column 6 and Figure 6A.]

Ramshaw et al. teaches a fusion polypeptide, wherein the polypeptide comprises i) a first amino acid sequence that comprises a cell-surface binding moiety, and ii) a second amino acid sequence that is a ligand for a cell surface polypeptide of a leukocyte. [Lines 55-62 of column 6 and Figure 6A.]

The first amino acid sequence used by Ramshaw et al. is that of influenza hemagglutinin. Hemagglutinin is a polypeptide that comprises a carbohydrate-binding domain of a naturally occurring lectin. In particular, the hemagglutinin polypeptide binds

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681-690.

[4] Ramshaw et al. U.S. Patent No. 5866131.

to the sialic acid is the carbohydrate-binding domain. Ergo, the first amino acid sequence provided by Ramshaw et al. comprises a cell-surface binding moiety.

The ligand that Ramshaw et al. teaches is interleukin-2 (IL2). Interleukin-2 (IL2) is a ligand for a cytokine receptor--interleukin-2 (IL2) receptor, which is a cell surface polypeptide of an antigen presenting cell, a professional antigen presenting cell, particularly dendritic cell. Thus, Ramshaw et al. teaches a second amino acid sequence that is a ligand for a cell surface polypeptide of a leukocyte.

The cell that Ramshaw et al. teaches is a mammalian cell. [Lines 55-62 of column 6]. The mammalian cell used by Ramshaw et al. has not been attenuated, thus, it is considered pathogenic.

Thus, Ramshaw et al. teaches a composition comprising a cell and a fusion polypeptide. The cell of Ramshaw et al. is the same as that instantly claimed. The same is also observed for the fusion polypeptide. Thus, Ramshaw et al. teaches the claimed composition.

Although it is noted that Ramshaw et al. is silent on the binding of the first amino acid to the cell, however, because the first amino acid sequence of Ramshaw et al. is capable of binding to a carbohydrate domain and the cell of Ramshaw et al. does have a cell-surface binding moiety-- a carbohydrate binding domain; the first amino acid sequence would necessarily bind to the cell.

Additionally, it is noted that the claims recite a "vaccine composition". The cited recitation has been considered, however, it is found that the recitation does not further limit the composition as claimed. The recitation "vaccine composition" suggests or

makes optional the use of the composition as a pharmaceutical. However, it does not require steps to be formed or does not limit the claims to a particular structure. Thus, it does not limit the scope of the claims.

Thus, Ramshaw et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbage et al., as applied to claims 1 and 5, in view of Galili et al.[5]

The claim requires that the cell be attenuated.

The relevance of Burbage et al. as it pertains to claims 1 and 5 is discussed above.

Burbage et al. does not teach a cell that is attenuated.

However, Galili et al. teaches the use autologous cancer cells to induce an antitumor immune response. [Page 501 to first full paragraph of page 502] Specifically, Galili et al. teaches the use of attenuated (irradiated) tumor cells. [Item No. 2 on page 508]

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[5] Galili et al. Cutting edge communication: Preparation of autologous leukemia and lymphoma vaccines expressing alpha Gal epitopes. Journal of Hematotherapy and Stem Cell Research, 2001, Vol. 10, 501-511.

In the instant, both Burbage et al. and Galili et al. are interested in providing an antitumor response. Burbage et al. teaches the use of an immunotoxin that is a fusion protein to target cancer cells to provide a form of cancer treatment. And Galili et al. teaches the use of attenuated tumor cells to provide an antitumor immune response. Thus, it would have been prima facie obvious for one of ordinary skill in the art the time the invention was made to combine the teachings of both Burbage et al. and Galili et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to optimize the antitumor immune response to a subject that is in need thereof. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Burbage et al. teaches the use of an immunotoxin that is a fusion protein to target cancer cells, and Galili et al. teaches the use of attenuated tumor cells to provide an antitumor immune response.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*,

422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which

can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/667193.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The

fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is that the claims in the instant application is directed at a product, and the claims in the conflicting patent application is directed at a method of using the same product as those provided in the claims in the instant application.

However, because the claims in the conflicting patent application is directed at a method of using a product that is the same as those provided in the claims in the instant application, it is clear that the conflicting patent application has possession of the instantly claimed product. Ergo, because the conflicting patent application has possession of the instantly claimed product, the conflicting patent application anticipates the instantly claimed product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of copending Application No. 10/645000.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

The one last difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule."

However, the ligands recited in claim 1 of the conflicting patent applications are all ligands for a cell surface polypeptide of a leukocyte. In the instant, claim 1 of the conflicting patent application falls entirely within the scope of claim 1 of the examined claimed. Hence, claim 1 of the conflicting patent application anticipates this aspect of the claim 1 of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/224661 in view of Faulkner et al.[6]

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin and a naturally occurring GM-CSF molecule.

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g., autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The other difference between the two set of claims is that claim 1 of instant patent application is directed to a genus of fusion polypeptides, whereas, claim 1 of the conflicting patent application is directed to a species of fusion polypeptides. The fusion polypeptide of claim 1 of the conflicting patent application falls entirely within the scope of the claim 1 of the instant patent application. The lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin is the first amino acid sequence that comprises a cell-surface binding moiety, and the naturally occurring GM-CSF molecule is the second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of copending Application No. 10/666898 in view of Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

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[6] Faulkner et al. IL-2 linked to a peptide from influenza hemagglutinin enhances T cell activation by affecting the antigen-presentation function of bone marrow-derived dendritic cells. International Immunology, 2001, Vol. 13, No. 6, 713-721.

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a nucleic acid composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to obtain the coding sequence of the fusion to express/make the fusion polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-147 of copending Application No. 10/666885 in view of Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The

fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vector comprising a nucleic acid molecule composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitation "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a vector construct comprising a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to place the vector expression construct in a cell to express/make the fusion polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending Application No. 10/666871, in view of Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/666834.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide. And the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application requires the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen; whereas claim 1 of the instant patent application does not require the same.

However, the antigen bearing target of claim 1 of the instant patent application is generic to the an antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen of claim 1 of the conflicting patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/667166.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

The other difference noted between the two claims is the recitations "first amino acid sequence which can bind to a carbohydrate" vs. "first amino acid sequence comprising a cell-surface binding moiety".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

29. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of copending Application No. 10/668073.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is that the claims in the instant application is directed at a product, and the claims in the conflicting patent application is directed at a method of using the same product as those provided in the claims in the instant application.

However, because the claims in the conflicting patent application is directed at a method of using a product that is the same as those provided in the claims in the instant application, it is clear that the conflicting patent application has possession of the instantly claimed product. Ergo, because the conflicting patent application has possession of the instantly claimed product, the conflicting patent application anticipates the instantly claimed product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

30. No claim is allowed.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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